

PHILLIPS, McLAUGHLIN & HALL, P.A.

JOHN C. PHILLIPS, JR.
LISA C. McLAUGHLIN*
JAMES P. HALL
DAVID A. BILSON***
MEGAN C. HANEY
TODD L. GOODMAN
PAUL S. SEWARD***

ALSO MEMBER OF
*PENNSYLVANIA BAR
**NEW JERSEY BAR
+MARYLAND BAR

ATTORNEYS AT LAW
PENNSYLVANIA AVE. AND BROOM ST.
1200 N. BROOM STREET
WILMINGTON, DELAWARE 19806

(302) 655-4200
(302) 655-4210 (F)
pmhdelaw.com

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VIA CM/ECF

Public Version

The Honorable Colm F. Connolly
United States District Court
for the District of Delaware
844 North King Street
Wilmington DE 19801

Re: *Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc., et al.*
C.A. No. 18-651-CFC (Cons.)

Dear Judge Connolly,

This firm represents defendants MSN Pharmaceuticals, Inc. and MSN Laboratories Pvt. Ltd. We write jointly with all parties to advise the Court of certain recently discovered disputes related to claim construction in this case, and to seek the Court's guidance on how it wants to resolve those disputes.

As background, the parties briefed various claim construction disputes in 2019 concerning U.S. Patent No. 10,077,977 (among others). The Court held a claim construction hearing on those disputes on October 10, 2019, and subsequently entered a Claim Construction Order (D.I. 105). The parties then engaged in expert discovery, including with respect to the '977 patent. Following the exchange of expert reports, it became clear that certain additional disputes remain about the construction of terms in the '977 patent that were not apparent during the initial claim construction process. The parties conferred and narrowed those disputes, but they were not able to fully resolve them.

Specifically, there are three terms in the '977 patent that the parties believe require construction: (1) "highly purified tasimelteon" in claim 22; (2) "purified tasimelteon" in claim 24; and (3) "analyzing" in claim 22. To date, the parties have not briefed any of those issues.

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The parties are also currently briefing certain claim construction disputes related to a separate patent (U.S. Patent No. 10,376,487) in a later filed case that was not in-suit at the time of the first claim construction hearing in October 2019. Briefing on those disputes was completed on August 5, 2020, and a claim construction hearing before Your Honor is scheduled for August 19, 2020. The '487 patent claim construction disputes are substantively unrelated to the remaining disputes over the '977 patent.

The parties are mindful of the added burden that the remaining disputes over the '977 patent places on the Court and they defer to the Court on how and when to address them. The parties have, however, discussed adjustments to the case schedule that they believe would allow adjudication of the '977 patent claim construction disputes prior to the trial currently set for July 19, 2021. The proposed changes are attached as Exhibit A to this letter. In short, the parties propose the following:

1. The parties would exchange claim terms and proposed constructions, file a joint claim chart and engage in a claim construction briefing process similar to what was done previously in the case. The parties propose that the maximum number of words they could use for briefing issues related to the '977 *and* '487 patents combined would not exceed the maximum number of words they are currently permitted to use for the '487 disputes alone. The briefing would conclude with the submission of a joint claim construction brief to the Court on September 4, 2020.

2. The Court would adjourn the currently scheduled August 19 claim construction hearing on the '487 patent to a date in late September or early October, as the Court's schedule allows, at which the parties would address both the '487 patent and '977 patent claim construction disputes.

The parties also have a dispute regarding steps (a)-(e) in claim 22 of the '977 patent:¹

¹ Defendants believe that what follows is a discovery dispute that should be handled according to the Court's standard procedures for raising and resolving discovery disputes. It should not be argued in an otherwise non-argumentative joint letter about procedures for addressing claim construction. Vanda nevertheless

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Vanda's Position: Defendants' rebuttal non-infringement expert report raised, for the first time in this litigation, Defendants' position that steps (a)-(e) of claim 22 of the '977 patent must be performed in a particular order. This construction was not addressed in any of the parties' claim construction briefing leading up to the Court's *Markman* hearing on October 10, 2019, nor was it raised by Defendants in their invalidity contentions, non-infringement interrogatory responses, or opening invalidity expert report. The parties' dispute is not about what the construction of steps (a)-(e) ought to be, but that Vanda has been prejudiced by this late-arising claim construction issue. Contrary to Defendants' suggestion, there is no presumption that the steps of a process claim be performed in any particular order, *see, e.g.*, *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342–43 (Fed. Cir. 2001), Vanda never had any cause to address or explore the order in which Defendants practice steps (a)-(e) of claim 22. Had this issue been raised at the appropriate time, Vanda would have had the opportunity to take fact discovery regarding Defendants' infringement of claim 22 under this particular construction in the normal course of the litigation. Vanda therefore asked Defendants if they would consent to Vanda serving one interrogatory and taking one one-hour 30(b)(6) deposition for each Defendant to permit Vanda the opportunity to determine whether and how Defendants' manufacturing processes for tasimelteon satisfies claim 22 under this new aspect of the construction. Defendants agreed to respond to an interrogatory but rejected Vanda's request for a deposition.

Vanda has been prejudiced by these untimely claim construction and non-infringement positions. To the extent these new positions are nonetheless permitted, Vanda respectfully requests that it be permitted to serve one interrogatory on each Defendant and take one one-hour 30(b)(6) deposition of each Defendant.

Defendants' Position: Vanda's request for additional discovery concerning steps (a)-(e) of claim 22 of the '977 patent should be denied because there is no "late-arising claim construction issue," and thus there is no conceivable resulting prejudice to Vanda.

insisted on inserting its position on this issue. Defendants have thus included their positions as well.

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Vanda is incorrect to characterize as “Defendants’ position” the fact that steps (a)-(e) must be performed in a particular order. *Every* party has always agreed that steps (a)-(e) must be performed in the order in which they were written, regardless of whether that is a legal presumption. That is why the order of steps (a)-(e) was not included as a “disputed” issue during the 2019 claim construction proceedings, and why no party is asking to address the order of the steps now as a claim construction dispute. Vanda even acknowledges in this letter that “The parties’ dispute is not about what the construction of steps (a)-(e) ought to be.” Moreover, Vanda is flatly wrong to suggest that Defendants did not previously “raise” this issue in previous documents (to the extent there is any need to “raise” as an issue the plain, ordinary and *agreed* meaning of a claim term). For example, Defendant MSN expressly provided noninfringement defenses based on the order of the steps in an interrogatory response served in November 2019. The discovery dispute Vanda now raises stems from the fact that Vanda’s expert appeared to give certain opinions about infringement that assumed steps (a)-(e) could be performed *out* of order. When confronted with that apparent inconsistency, however, Vanda has never offered a construction that differs from the Defendants’ view.

It thus makes no sense for Vanda to argue that there is a “late-arising claim construction issue” that creates the need for more discovery. Claim 22 is directed to a process for making tasimelteon. Vanda proceeded through fact discovery on that process claim with the same understanding of the order of steps that it has now. With that understanding, Vanda took all manner of discovery about the steps by which Defendants manufacture their accused drug products. Vanda requested documents that “describe the current, proposed, and anticipated *process(es)* used to synthesize, purify, manufacture, and/or test... any Tasimelteon Product that is the subject of an ANDA.” (Document Request No. 18 to MSN, Ex. B (emphasis added).) Defendants produced those documents. Vanda served interrogatories that demanded a description of “any current, proposed, or future-planned methods and *processes* to manufacture, synthesize, purify, and test the Tasimelteon Product, including but not limited to all protocols, specifications....” (Joint Interrogatory No. 8, Ex. C (emphasis added). Defendants responded. Vanda sought Rule 30(b)(6) deposition testimony concerning “The method for preparing, synthesizing, analyzing, purifying, and manufacturing the tasimelteon drug substance, tasimelteon drug product, and capsules of tasimelteon drug product for the product(s) covered by” the Defendants’ ANDAs. (E.g., Deposition Topic 19 to MSN, Ex. D.) Defendants prepared and presented witnesses on that subject matter. Vanda has not identified any other information it might get from Defendants about the steps used to make their products that it did not previously ask for and receive

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from Defendants. It says it had no “cause to address or explore the order in which Defendants practice steps (a)-(e) of claim 22.” But it did address and explore that order. The documents it sought, interrogatories it served and deposition testimony it took about the manufacturing *processes* are by definition related to the order in which steps are performed.²

Vanda’s request is thus revealed as an effort to prejudice Defendants. It seeks new written fact discovery and fact deposition testimony *after* the parties have already exchanged the main expert reports on infringement and invalidity of the ’977 patent. Vanda should not get that second chance to fill gaps in its case that it had every chance to fill during the initial round of fact discovery, when all parties had the same understanding of the order of steps (a)-(e) that they have today. Vanda’s request for Vanda’s request for additional discovery should therefore be denied.³

* * *

The parties respectfully request a teleconference with the Court at the Court’s convenience to discuss these issues.

Respectfully,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)

Enc.
cc: All counsel of record (via email)

² Lexico.com, powered by Oxford, defines “process” as “A series of actions or steps taken *in order* to achieve a particular end” and “A systematic series of mechanized or chemical operations that are performed *in order* to produce or manufacture something.” See <https://www.lexico.com/en/definition/process> (emphasis added).

³ In an effort to compromise and resolve this dispute without burdening the Court, Defendants offered to allow Vanda one additional interrogatory. Vanda rejected that compromise offer and has insisted on obtaining additional deposition testimony as well.